Multicenter Studies of Trabecular Metal Dental Implants: 3-Year Interim Results

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1 Background

Several factors, such as the characteristics of implant surface and density of the surrounding bone tissues, can influence the percentage of bone attachment.[1] Over the years, various modifications have been introduced to the implant surface such as, a porous coating, to increase the percentage of bone attachment[1].

Pore size and porosity are determining factors for successful bone ingrowth.[2] Because pore sizes tended to be irregular and porosity extremely limited in traditional surface coatings, a biomimetic approach was used to develop a highly porous, tantalum material which simulates the structure and elasticity of trabecular bone[2]. The material provides up to 75-80% porosity through a network of interconnected pores to support bone formation and vascularization inside the material[2]. Trabecular Metal dental implants utilize this characteristic to supplement anchorage through a combination of bone ingrowth and bone ongrowth, which is termed osseoincorporation[3].

2 Objectives and Study Design

This poster provides a 3-year update on 2 ongoing clinical studies with Trabecular Metal™ (TM) dental implants. Both studies are being conducted under the auspices of local research ethics committees and have enrolled subjects with partially edentulous jaw(s). Each patient was treated with up to two TM implants.

Study No. 1: Immediate Loading (IL) Study

A 5-year proof-of-principle study was initiated at 2 centers to evaluate the efficacy of immediately loaded TM dental implants in the posterior jaw. Smokers and sites with type 4 bone were excluded. Implants which achieved ≥35 Ncm insertion torque were included and provisionalized out of occlusion within 48 hours and definitively restored within two weeks, of placement.

Study No. 2: Longitudinal Data Collection Program (LDCP)

A 5-year Longitudinal Data Collection Program (LDCP) was launched to collect data on TM dental implants placed in routine clinical practice in an uncontrolled population while following the implant's instructions for use (IFU). Many enrolled subjects presented with elevated risks for bone loss or implant failure (light smoking, history of periodontal disease, and type 4 bone etc).

3 Results

Study No. 1: Thirty patients were treated per protocol with 37 implants; one patient with a single implant was lost to follow up. In the remaining 29 patients and 36 implants, one implant failed to osseointegrate, which resulted in a cumulative survival rate of 97.2% (N=36/37). To date, 19 subjects with 24 implants completed three years of follow up with 100% survival (n=24/24). The mean change in bone level from provisional restoration to 3-year follow up is 0.46±0.52mm. *Figure 1 shows the radiographs and clinical photos of a representative case.*

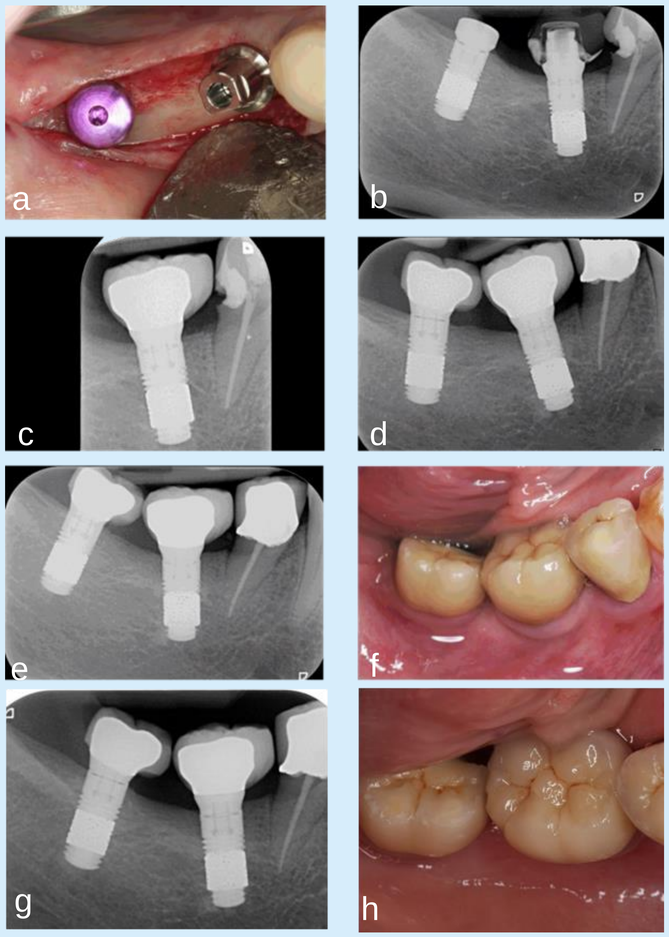

Figure 1. Radiographs and clinical views of a female patient in the IL study presented with a healed edentulous space in the mandibular right first molar area for placement (a) and sufficient stabilization (b) of a TM dental implant (4.7mmD x 10mmL). After 2 weeks a final restoration (c) was delivered. The implant maintained soft tissue levels and exhibited no complications at the 1- (d), 2- (e, f) and 3- (g, h) year follow-up visits. At the 3-year visit, the implant was stable and fully functional with minimal crestal bone loss (0.12 mm). The TM implant in the mandibular right second molar area was a non-study implant followed conventional loading. *Case contributed by Dr Markus Schlee.*

		Study No. 1	Study No. 2
Age (years)	*Average*	45.47	54.84
	Minimum	19	22
	Maximum	73	77
Gender	*Male*	11	53
	Female	19	64
Location	*Maxilla*	10 implants	59 implants
	Mandible	27 implants	104 implants
Bone Density Classification[4]	*Type I*	-	19 implants
	Type II	23 implants	71 implants
	Type III	14 implants	50 implants
	Type IV	-	20 implants

Table 1. Summary of patient demographics, implant design and location, and bone density classification

Study No. 2:The study enrolled 304 patients who were treated with 428 implants. To date, 117 patients with 163 implants were recalled for the 3-year visit. Within this group, 44 (37.6%) patients with 63 (38.7%) implants had elevated risk factors for bone loss or implant failure; three patients with 3 implants were lost to follow up and one patient with a single implant died of systemic disease (cancer) unrelated to the study device. In the remaining 113 patients with 159 implants, 5 implants failed, which resulted in a cumulative survival rate of 96.9% (n=154/159). Implant survival in the healthy group was 96.9% (n=95/98) and 96.7% (n=59/61) in the group with elevated risks.

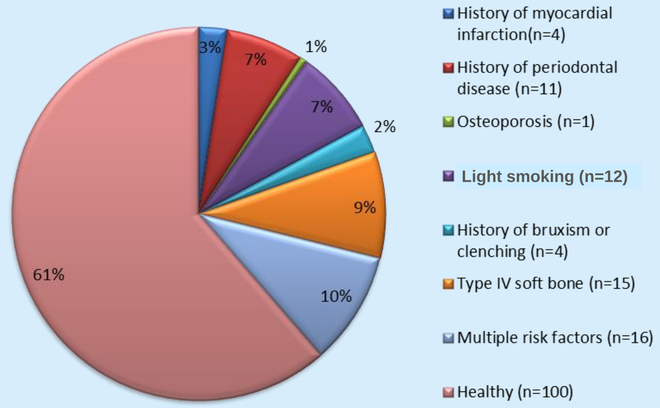

Table 2. Increased concomitant risk factors for Implant failure and/or crestal bone loss in 117 patients treated with 163 Implants (Study No. 2)

4 Conclusion

Within the limitations of these studies:

- TM dental implants were clinically effective under immediate loading conditions in a controlled study
- TM dental implants were clinically effective in patients typically expected to be seen in practice.

5 References

1. Spector M. Historical review of porous coated implants. J Arthroplasty 1987; 2:16.-177.
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4. Lekholm U, Zarb GA. In: Branemark PI et al. Tissue-Integrated Prostheses. Osseointegration in Clinical Dentistry. Chicago: Quintessence Publishing Co., Inc. 1985:199-209.

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